

## CLAIMS

1. (Currently Amended) A system for analyzing medical devices comprising:
  - a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s);
    - a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device; and
    - a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said medical device.
2. (Previously Presented) The system of claim 1 wherein said geometric model of said anatomical feature(s) is an idealized geometric model.
3. (Previously Presented) The system of claim 1 wherein said three-dimensional volumetric data are acquired via CT scan.
4. (Previously Presented) The system of claim 1 wherein said three-dimensional volumetric data are acquired via MRI.
5. (Previously Presented) The system of claim 1 wherein said medical device is an endovascular prosthesis.
6. (Previously Presented) The system of claim 5 wherein said endovascular prosthesis is a stent graft.
7. (Previously Presented) The system of claim 5 wherein said endovascular prosthesis is a cardiovascular stent.
8. (Previously Presented) The system of claim 1 wherein said geometry generator is a software application which generates surface points from the three-dimensional

volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

9. (Previously Presented) The system of claim 1 wherein said mesh generator includes three-dimensional finite modeling software.

10. (Previously Presented) The system of claim 1 wherein said stress/strain/deformation analyzer is a non-linear finite element modeling software application.

11. (Previously Presented) The system of claim 9 wherein said three dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

12. (Previously Presented) The system of claim 10 wherein said non-linear finite element modeling software application is configured to accommodate a strain energy density of the form:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{30}(I_1 - 3) + a_{21}(I_1 - 3)^2(I_2 - 3) + a_{12}(I_1 - 3)(I_2 - 3)^2 + a_{03}(I_2 - 3)^3 + 1/2K(I_3 - 1)^2$$

with  $K = 2(a_{10} + a_{01})/(1-2v)$  where

$a_{ij}$  are material parameters;

$v$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

13. (Canceled )

14. (Previously Presented) The system of claim 1 further comprising a visualization tool that receives said simulated stresses, strains, and deformations of said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation.

15. (Previously Presented) The system of claim 14 wherein said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids.

16. (Currently Amended) A system for analyzing a medical device comprising:
  - a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a vascular system of a particular individual and generates a geometric model of said anatomical feature(s);
  - a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said medical device; and
  - a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformation of said medical device.
17. (Previously Presented) The system of claim 16 wherein said geometric model of said anatomical feature(s) is an idealized geometric model.
18. (Previously Presented) The system of claim 16 wherein said three dimensional volumetric data are acquired via CT scan.
19. (Previously Presented) The system of claim 16 wherein said three dimensional volumetric data are acquired via MRI.
20. (Previously Presented) The system of claim 16 wherein said medical device is an endovascular prosthesis.
21. (Previously Presented) The system of claim 20 wherein said endovascular prosthesis is a stent graft.
22. (Previously Presented) The system of claim 20 wherein said endovascular prosthesis is a cardiovascular stent.
23. (Previously Presented) The system of claim 16 wherein said geometry generator is a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

24. (Previously Presented) The system of claim 16 wherein said mesh generator includes three-dimensional finite modeling software.
25. (Previously Presented) The system of claim 16 wherein said stress/strain/deformation analyzer is a non-linear finite element modeling software application.
26. (Previously Presented) The system of claim 24 wherein said three dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.
27. (Previously Presented) The system of claim 25 wherein said non-linear finite element modeling software application is configured to accommodate a strain energy density of the form:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{30}(I_1 - 3) + a_{21}(I_1 - 3)^2(I_2 - 3) + a_{12}(I_1 - 3)(I_2 - 3)^2 + a_{03}(I_2 - 3)^3 + 1/2K(I_3 - 1)^2$$

with  $K = 2(a_{10} + a_{01})/(1-2v)$  where

$a_{ij}$  are material parameters;

$v$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

28. (Canceled)
29. (Previously Presented) The system of claim 16 further comprising a visualization tool that receives said simulated stresses, strains, and deformations of said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation.
30. (Previously Presented) The system of claim 29 wherein said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids.
31. (Currently Amended) A system for analyzing a medical device comprising:
  - a mesh generator that receives a geometric model of an in vitro anatomical feature of a vascular system and a geometric model of a medical

device, and generates a finite element model or mesh representing both said geometric model of said in vitro anatomical feature and said geometric model of said medical device; and;

a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said in vitro anatomical feature and said medical device, load data on said in vitro anatomical feature and/or said medical device and simulates an interaction between said in vitro anatomical feature and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said medical device.

32. (Previously Presented) The system of claim 31 wherein said in vitro anatomical feature is idealized.
33. (Previously Presented) The system of claim 31 wherein said medical device is an endovascular prosthesis.
34. (Previously Presented) The system of claim 33 wherein said endovascular prosthesis is a stent graft.
35. (Previously Presented) The system of claim 33 wherein said endovascular prosthesis is a cardiovascular stent.
36. (Previously Presented) The system of claim 31 wherein said mesh generator includes three-dimensional finite modeling software.
37. (Previously Presented) The system of claim 31 wherein said stress/strain/deformation analyzer is a non-linear finite element modeling software application.
38. (Previously Presented) The system of claim 36 wherein said three dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.
39. (Previously Presented) The system of claim 37 wherein said non-linear finite element modeling software application is configured to accommodate a strain energy density of the form:

$$W = a_{10}(l_1 - 3) + a_{01}(l_2 - 3) + a_{20}(l_1 - 3)^2 + a_{11}(l_1 - 3)(l_2 - 3) + a_{02}(l_2 - 3)^2 + a_{30}(l_1 - 3) + a_{21}(l_1 - 3)^2(l_2 - 3) + a_{12}(l_1 - 3)(l_2 - 3)^2 + a_{03}(l_2 - 3)^3 + 1/2K(l_3 - 1)^2$$

with  $K = 2(a_{10}+a_{01})/(1-2v)$  where

$a_{ij}$  are material parameters;

$v$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

40. (Canceled)

41. (Previously Presented) The system of claim 31 further comprising a visualization tool that receives said simulated stresses, strains, and deformations of, said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation.

42. (Previously Presented) The system of claim 41 wherein said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids.

Claims 43-53 Canceled

54. (Currently Amended) A computer method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature of a vascular system;

generating a geometric model of said anatomical feature(s);

receiving data representing a geometric model of a candidate medical device design;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said candidate medical device design and said anatomical feature(s); and

simulating an interaction between said anatomical feature(s) and said

candidate medical device design over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data.

55. (Previously Presented) The method of claim 54 wherein the step of simulating stresses, strains, and deformations is performed to a point of failure of said candidate medical device design.

56. (Previously Presented) The method of claim 54 wherein where said three-dimensional volumetric data are acquired via CT scan.

57. (Previously Presented) The method of claim 54 wherein said three-dimensional volumetric data are acquired via MRI.

58. (Previously Presented) The method of claim 54 wherein said candidate medical device design is for an endovascular prosthesis.

59. (Previously Presented) The method of claim 58 wherein said endovascular prosthesis is a stent graft.

60. (Previously Presented) The method of claim 58 wherein said endovascular prosthesis is a cardiovascular stent.

61. (Previously Presented) The method of claim 54 wherein said geometric model for said anatomical feature(s) is generated by a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

62. (Previously Presented) The method of claim 54 wherein said step of generating a finite element model or mesh is performed by using includes three-dimensional finite modeling software.

63. (Previously Presented) The method of claim 54 wherein said stresses, strains, and deformations are simulated by a non-linear finite element modeling software application.

64. (Previously Presented) The method of claim 62 wherein said three dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

65. (Previously Presented) The method of claim 63 wherein said non-linear finite element modeling software application is configured to accommodate a strain energy density of the form:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{30}(I_1 - 3) + a_{21}(I_1 - 3)^2(I_2 - 3) + a_{12}(I_1 - 3)(I_2 - 3)^2 + a_{03}(I_2 - 3)^3 + 1/2K(I_3 - 1)^2$$

with  $K = 2(a_{10} + a_{01})/(1-2v)$  where

$a_{ij}$  are material parameters;

$v$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

66. (Canceled)

67. (Previously Presented) The method of claim 54 wherein said stress/strain/deformation analysis is performed using a non-linear finite element analysis tool.

68. (Previously Presented) The method of claim 54 further comprising receiving results of said stress, strain, and deformation analysis into a visualization tool and wherein said visualization tool visually presents one or more of said strains, stresses, and deformations of said medical device.

69. (Previously Presented) The method of claim 68 wherein said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids.

70. (Currently Amended) A method for analyzing a medical device comprising:  
acquiring three-dimensional volumetric data of at least one anatomical feature of a vascular system of a particular individual;  
generating a geometric model of said anatomical feature(s);  
receiving a geometric model of a candidate medical device;  
receiving said geometric model of said anatomical feature(s);  
generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said

candidate medical device;

receiving material properties of said anatomical feature(s) and said candidate medical device;

receiving load data imposed on said anatomical feature(s) and said candidate medical device; and

simulating an interaction between said anatomical feature(s) and said candidate medical device the stress/strain/deformation analyzer simulates an interaction between the anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device.

71. (Previously Presented) The method of claim 70 wherein the step of simulating stresses, strains, and deformations is performed to a point of failure of said candidate medical device.

72. (Previously Presented) The method of claim 70 wherein where said three-dimensional volumetric data are acquired via CT scan.

73. (Previously Presented) The method of claim 70 wherein said three-dimensional volumetric data are acquired via MRI.

74. (Previously Presented) The method of claim 70 wherein said candidate medical device is an endovascular prosthesis.

75. (Previously Presented) The method of claim 74 wherein said endovascular prosthesis is a stent graft.

76. (Previously Presented) The method of claim 74 wherein said endovascular prosthesis is a cardiovascular stent.

77. (Previously Presented) The method of claim 70 wherein said step of generating the geometric model of said anatomical feature(s) is performed by using a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

78. (Previously Presented) The method of claim 70 wherein said step of generating said mesh is performed by using includes three-dimensional finite modeling software.

79. (Previously Presented) The method of claim 70 wherein said step of simulating dynamic or quasi-static stresses/strains/deformations is performed by using a non-linear finite element modeling software application.

80. (Previously Presented) The method of claim 78 wherein said three dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

81. (Previously Presented) The method of claim 79 wherein said non-linear finite element modeling software application is configured to accommodate a strain energy density of the form:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{30}(I_1 - 3) + a_{21}(I_1 - 3)^2(I_2 - 3) + a_{12}(I_1 - 3)(I_2 - 3)^2 + a_{03}(I_2 - 3)^3 + 1/2K(I_3 - 1)^2$$

with  $K = 2(a_{10} + a_{01})/(1-2v)$  where

$a_{ij}$  are material parameters;

$v$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

82. (Canceled)

83. (Previously Presented) The method of claim 70 wherein said stress/strain/deformation analysis is performed using a non-linear finite element analysis tool.

84. (Previously Presented) The method of claim 70 further comprising receiving results of said stress, strain, and deformation analysis into a visualization tool and wherein said visualization tool visually presents one or more of said strains, stresses, and deformations of said medical device.

85. (Previously Presented) The method of claim 84 wherein said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids.

86. (Currently Amended) A computer method for analyzing a medical device comprising:

receiving data representing a geometric model of at least one in vitro anatomical feature of a vascular system and a geometric model of a candidate medical device design;

generating a finite element model or mesh representing both said geometric model of said in vitro anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said in vitro anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said in vitro anatomical feature(s) and said candidate medical device design; and

simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device the stress/strain/deformation analyzer simulates an interaction between the anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data.

87. (Previously Presented) The method of claim 86 wherein the step of simulating stresses, strains, and deformations is performed to a point of failure of said candidate medical device design.

88. (Previously Presented) The method of claim 86 wherein said geometric model of said candidate medical device design is for an endovascular prosthesis.

89. (Previously Presented) The method of claim 88 wherein said endovascular prosthesis is a stent graft.

90. (Previously Presented) The method of claim 88 wherein said endovascular prosthesis is a cardiovascular stent.

91. (Previously Presented) The method of claim 86 wherein said step of generating said mesh is performed by using includes three-dimensional finite modeling software.

92. (Previously Presented) The method of claim 86 wherein said step of simulating stresses, strains, and deformations is performed by using a non-linear finite element modeling software application.

93. (Previously Presented) The method of claim 91 wherein said three dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

94. (Previously Presented) The method of claim 92 wherein said non-linear finite element modeling software application is configured to accommodate a strain energy density of the form:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{30}(I_1 - 3) + a_{21}(I_1 - 3)^2(I_2 - 3) + a_{12}(I_1 - 3)(I_2 - 3)^2 + a_{03}(I_2 - 3)^3 + 1/2K(I_3 - 1)^2$$

with  $K = 2(a_{10} + a_{01})/(1-2v)$  where

$a_{ij}$  are material parameters;

$v$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

95. (Canceled)

96. (Previously Presented) The method of claim 86 wherein said stress/strain/deformation analysis is performed using a non-linear finite element analysis tool.

97. (Previously Presented) The method of claim 86 further comprising the step of receiving results of said stress, strain, and deformation analysis into a visualization tool and wherein said visualization tool visually presents one or more of said strains, stresses, and deformations of said candidate medical device design.

98. (Previously Presented) The method of claim 97 wherein said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids.

Claims 99-111 (Canceled)

112. (Previously Presented) The system of claim 1 wherein said stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate said stresses, strains, and deformations of said medical device.

113. (Previously Presented) The system of claim 1 wherein said simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations.

114. (Previously Presented) The system of claim 16 wherein said stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate stresses, strains, and deformations of said medical device.

115. (Previously Presented) The system of claim 16 wherein said simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations.

116. (Previously Presented) The system of claim 31 wherein said stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate stresses, strains, and deformations of said medical device.

117. (Previously Presented) The system of claim 31 wherein said simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations.

118. (Previously Presented) The method of claim 54 wherein said simulated stresses, strains, and deformations imposed on said medical device design comprise dynamic or quasi-static stresses, strains, and deformations.

119. (Previously Presented) The method of claim 86 wherein said simulated stresses, strains, and deformations imposed on said candidate medical device design comprise dynamic or quasi-static stresses, strains, and deformations.

120. (Previously Presented) The method of claim 86 further comprising receiving data representing a geometric model for use in an in vitro failure mode test.

121. (Previously Presented) The method of claim 120 wherein said step of simulating comprises simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said in vitro failure mode test.

122. (Previously Presented) The method of claim 120 further comprising varying one or more in vitro failure mode test parameters based on an additional step of comparing:  
simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data representing said anatomical feature; and

additional simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said in vitro failure mode test.

123. (Previously Presented) The method of claim 122 wherein said one or more in vitro failure mode test parameters further comprises test frequency.

124. (New) The method of claim 70 further comprising long term structural integrity testing of said medical device by recreating a large number of dynamic expansion and contraction cycles of the vascular system.

125. (New) The method of claim 124 wherein the large number of dynamic expansion and contraction cycles of the vascular system comprise an amount of cycles that would meet or exceed the amount of cycles that would be expected in the individual's lifetime.

126. (New) The method of claim 54 further comprising simulating testing necessary or desirable for FDA approval of the medical device.

127. (New) The method of claim 126 further comprising simulating testing necessary to establish equivalence of the medical device with an approved medical device.